

SECTION 3
quantex C4 - 510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

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SEP 26 1996

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Summary Prepared:

May 29, 1996

Name of the device:

quantex C4:	8 x 6 mL anti-human C4	P/N 3000-22137
	2 x 100 mL Buffer	P/N 3000-22130

Classification name(s):

866.5240 Complement components immunological test systems Class II

Identification of predicate device(s):

IL Test™ C4 #K920010/B

Description of the device/intended use(s):

This product permits the quantitative *in vitro* diagnostic determination of Complement 4 in serum and plasma on the ILab Clinical Chemistry System by turbidimetric immunoassay method. C4 is one of a group of serum proteins which destroy infectious agents. Measurement of this protein aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of C4.

Statement of how the Technological Characteristics of the Device compare to the Predicate device:

Biokit's quantex C4 is substantially equivalent in performance, intended use, safety and effectiveness to the predicate, IL Test™ C4 -- 510(k) #K920010/B.

Summary of Performance Data:

A comparative performance study was performed with IL Test™ C4 on a Monarch Clinical Chemistry System and Biokit's quantex C4 on an ILab Clinical Chemistry System. Method comparison studies evaluated C4 levels of thirty-eight serum samples on the respective instruments. The correlation (*r*) in these studies was 0.9791.